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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,096	01/27/2004	Ching-I Patsy Lin	02558B-059130US	3204

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EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	**PAPER NUMBER**
BPAI	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,096	LIN ET AL.	
	Examiner	Art Unit	
	Francisco C. Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendments filed January 27, 2004, and August 16, 2004, have been received and entered.

Claims 14-17 are pending and are examined on the merits.

Claim Objections

Claims 15-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 14 recites a "collection of standardized, sealed vials" whereas dependent claims 15-17 all recite "A sealed vial of claim 14". Because claims 15-17 require only one vial and claim 14 requires a plurality of vials, claims 15-17 cannot properly depend from claim 14.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-17 are rejected under 35 U.S.C. 101 because the

claimed invention is directed to non-statutory subject matter. While it appears that applicant intends to claim a ***kit*** comprising "[a] collection of standardized sealed vials . . ." the current claim language "collection" appears to fall outside the categories enumerated in § 101 because applicant's claims recite multiple compositions of matter, rather than a single product as required by § 101. Note that amending the claims to recite a kit comprising sealed vials would overcome this ground of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "collection" in claim 14 is indefinite because it is not clear what subject matter is encompassed by the language. While it is conceded that the term "collection" has a fairly well accepted meaning in everyday parlance, the

metes and bounds of the term are not clear in this context because the relationship and proximity between the various vials is not clear. That is, it is not clear how close the vials must be to each other to be considered a "collection", nor is it clear what sort of relationship or arrangement the vials must have to be considered to be a "collection."

The term "standardized" in claim 14 is indefinite because it is not clear how one can tell whether a particular vial is "standardized" or not. The metes and bounds of the term are simply not clear.

Claims 15-17 are indefinite because they recite "A sealed vial" of claim 14, whereas claim 14 recites "A collection of standardized, sealed vials". Thus, claims 15-17 require only one vial whereas claim 14 requires a plurality. Thus, claims 15-17 are confusing when viewed in light of claim 14, and are therefore indefinite.

The recitation "reduce degradation of RNA" in claim 17 is indefinite because it is not clear what the RNA degradation is being compared to, such that one can determine whether a reduction has occurred.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14 and 16 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kortright et al (U.S. Pat. 5,059,518).

The reference discloses a product which appears to be identical to the presently claimed product, based on the fact that the prior art discloses a group of sealed vials of T-cells lyophilized in trehalose-treated isotonic buffer. *See, e.g.,* col. 6, lines 35-42. Note specifically that applicant's claims require only that the cells be lyophilized. Thus, the prior art discloses a product which is produced by a process having every one of the process steps recited in the claims. Consequently, the claimed product appears to be anticipated by the reference.

It is noted that the reference does not mention anything about the degree to which the 18S rRNA remains intact after storage for 4 weeks at -20°C. However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that maintaining cell integrity, as measured by RNA degradation, is desirable. Moreover, the flow cytometer histograms (Fig. 1) clearly suggest that the cells in the prior art are very intact after lyophilization. Thus the

claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallo et al (U.S. Pat. 4,520,113) in view of Kortright et al (U.S. Pat. 5,059,518).

Gallo discloses the use of HIV-infected T-cells in assays for determination of the presence of anti-HIV antibodies. *See, e.g.,* Gallo '113 at col. 5, line 62 through col. 6, line 3. Gallo differs from the claims in that Gallo does not disclose the cells in a group or collection of sealed, standardized vials. However, Kortright clearly discloses the advantages of maintaining a stock of sealed vials of lyophilized cells, including T-cells, for use as biological controls in various assays, including immunological assays. *See, e.g.,* Kortright '518 at col. 4, line 45 through col. 5, line 11. Thus, the artisan of ordinary skill, recognizing from Kortright the advantages of maintaining a stock of sealed vials of lyophilized cells for use in immunoassays, clearly would have been motivated by the advantages disclosed by Kortright to have lyophilized the

HIV-infected cells of Gallo in order to save the cells for later use in Gallo's assays.

The artisan of ordinary skill would reasonably have expected the methods of Kortright to function equivalently using Gallo's cells, in view of the fact that Gallo's cells are lymphocytes, the exact type of cell disclosed by Kortright as being amenable to the preservation techniques disclosed therein. Further still, the artisan of ordinary skill clearly would have been motivated to have included an RNase inhibitor in the preparation because the RNase inhibitor would have been reasonably expected to improve the viability and integrity of the HIV virus included in Gallo's preparation. It is therefore respectfully submitted that a holding of obviousness is proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

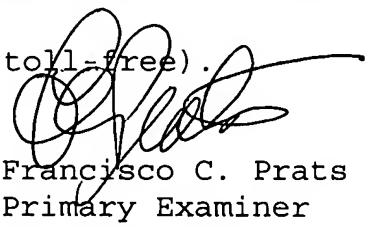
Claims 14-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,410,321. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "kit" recited in the patented claims can be considered a "collection" as recited in the claims under examination, and because the patented claims recites the same cell types having the same rRNA intactness as recited in the claims under examination, and because the patented claims' recitation of rRNA intactness suggests the presence of an Rnase inhibitor. A terminal disclaimer is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats
Primary Examiner
Art Unit 1651

FCP